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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/624,997      | 07/23/2003  | Peter Fuenfschilling | 100-8345E           | 8182             |

1095 7590 11/25/2005

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

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| EXAMINER |
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SHIRALI, SHYAM S

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                       |  |
|------------------------------|------------------------|-----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>   |  |
|                              | 10/624,997             | FUENFSCHILLING ET AL. |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>       |  |
|                              | Shyam Shirali          | 1654                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-48 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-17 and 19-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/03</u>   | 6) <input type="checkbox"/> Other: ____                                     |

## DETAILED ACTION

### Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I claims 11 – 17, 19-48 are drawn to a product Cyclosporine A

Classified in class 514/9 (cyclicpeptides) subclass 2

Group II claim 18, is drawn to a countercurrent extraction column.

Classified in class 210/294

2.. Inventions group I and group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case they different inventions because they are two different methods or processes. Neither product is required to make or use the other, neither would render the other obvious, and a separate search is required for each.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Ann Hess on 10/24/2005 a provisional election was made with traverse to prosecute the invention of group I, claims 11 – 17, 19 - 48. Affirmation of this election, product cyclopsorin A must be made by applicant in

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replying to this Office action. Claim 18 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are 11-17, 19-48 are rejected under 35U.S.C.102(b) as being anticipated by Wenger et. al. (Helvetica Chimica Acta 1984, 67, 503-515.)

The claims 11-17, 19-48 are drawn to purified Cyclosporin produced by HSCCC

The reference disclose the synthesis, purification and structure confirmation

by analytical methods which is encompassed by the claimed invention. The structure of this molecule is very well determined as well as the purity of the compound (more than 98.5%.) The pure compound is also available.

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Although the references does not teach the process of purification by HSCCC, the references still anticipate the claims. This is because

[E]ven though product – by- process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on the method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” In re Thorpe, 777 F2d 695, 698, 227 USPQ 964,966 (Fed. Cir.1985).

Therefore claims 11 – 17, 19 – 48 are rejected.

#### **Conclusion**

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shyam Shirali whose telephone number is (571)-272-5547. The examiner can normally be reached on 8.00am to 4.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Bruce Campell can be reached on (571) 272- 0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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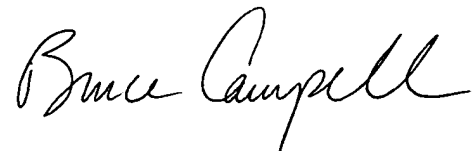
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shyam Shirali

Patent Examiner

Office: Remsen 3D10,

571-2725547



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